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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,218	06/25/2004	Yoshihiro Horiuchi	2004-0979A	3293

513 7590 12/11/2007

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,218	HORIUCHI, YOSHIHIRO	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6,9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Status of Claims

Claims 1-19 are pending.

Claims 1-18 are rejected.

Claim 19 has been withdrawn from consideration.

DETAILED ACTION

1. Claims 1-18 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/JP02/13580 (12/26/2002) ,which has a foreign priority document, Japan 2001-397638 (12/27/2001).

Drawings

3. None.

Election/Restrictions

Applicant's election without traverse of Group I, namely Claims 1-18 (non-heterocylic hydroxamic acid derivative) on 09/20/07 is acknowledged.

Groups II and III are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups II-III, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and their corresponding dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the claims 1-12, the term " prodrug" is recited. However, the specification has not described how any prodrug is converted into its active form in the body under any circumstances. This description is essential to the claimed invention because it allows to distinguish identifying characteristics sufficient show that the applicant was in possession of the claimed invention, and the claim ,as a whole, may not be adequately described where the invention is described solely in terms of a process of its conversion coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its functional language. For example, Medical dictionary defines the term as a class of drugs, initially

in active form, that are converted into active form in the body by normal metabolic processes. There are no examples for how the prodrugs are converted or metabolized to the active compound of the present invention.

Therefore, the specification has failed to describe the subject matter in the claims as to the relationship between the prodrugs and their final active claimed compounds during the metabolizing process. Therefore, an appropriate correction is required.

Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 15-18, the phrase " a prophylactic agent for a disease related to promotion of MMP-3 and /or MMP-13 containing a hydroxamic acid derivative or its prodrug" is recited. However, the specification does not describe how to prevent prophylactically a disease related to promotion of MMP-3 and /or MMP-13 containing the hydroxamic acid derivative or its prodrug and also, there are no showings of any evidence for the prophylactic agent for a disease related to promotion of MMP-3 and /or MMP-13 at the same time. Furthermore, the contemporary knowledge of the art does not teach " how to prevent " for all the alleged diseases related to promotion of MMP-3 and /or MMP-13 containing the hydroxamic acid derivative or its prodrug. If we could prevent all the possible permutations and combinations of the above, nobody

would be sick. In addition, more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al. , 190 USPQ 152 (CCPA 1990). Therefore, the specification has failed to support enablement for the prophylactic agent for a disease related to promotion of MMP-3 and /or MMP-13 containing a hydroxamic acid derivative or its prodrug. Therefore, an appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-12, and 15 , the term "derivative" is recited. This expression is vague and indefinite because the specification does not elaborate what is meant by the term "derivative".

Therefore, an appropriate correction is required.

In claims 1 and 7, the term "substituted" is indefinite. In the absence of the specific moieties intended to effectuate modification by the "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to

identifying the composition of matter claimed. Therefore, an appropriate correction is required.

In claims 12 and 15 , " the MMP-3 and/or MMP-13 containing" is recited. This expression is vague and indefinite because it would mean there are other additional ingredients present in the MMP-3 and/or MMP-13; however, the skilled artisan in the art is unable to figure out what the unspecified additional ingredients are . Therefore, an appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Status of Claims

Claims 1-19 are pending.

Claims 1-18 are rejected.

Claim 19 has been withdrawn from consideration.

DETAILED ACTION

1. Claims 1-18 are under consideration in this Office Action.

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3. None.

Election/Restrictions

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Groups II and III are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups II-III, there being no allowable generic or linking claim.

Claim Objections

Claims 1,6-7,10 are objected to because of the following informalities:

In claim 1, " R1 together with their binding N atom and carbon atom to form optionally substituted heterocycloalkane" is recited.

In claims 6 and 10, " 2-pyridyl group, 3-pyridyl group, 4-pyridyl group, furyl group, thienyl group (the said pyridyl group, furyl group, and thienyl group may be substituted by loewe alkyl group" is recited.

In claim 7, " optionally substituted pyrrolidine, pyridine, piperazine, morpholine or thiomorpholine" is recited. All those limitations are directed to the non-elected group II; they must be removed from the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and their corresponding dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the claims 1-12, the term " prodrug" is recited. However, the specification has not described how any prodrug is converted into its active form in the body under any circumstances. This description is essential to the claimed invention because it allows to distinguish identifying characteristics sufficient show that the applicant was in possession of the claimed invention, and the claim ,as a whole, may not be adequately described where the invention is described solely in terms of a process of its conversion coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its functional language. For example, Medical dictionary defines the term as a class of drugs, initially in active form, that are converted into active form in the body by normal metabolic processes. There are no examples for how the prodrugs are converted or metabolized to the active compound of the present invention.

Therefore, the specification has failed to describe the subject matter in the claims as to the relationship between the prodrugs and their final active claimed compounds during the metabolizing process. Therefore, an appropriate correction is required.

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Therefore, an appropriate correction is required.

In claims 1 and 7, the term "substituted" is indefinite. In the absence of the specific moieties intended to effectuate modification by the "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed. Therefore, an appropriate correction is required.

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TAYLOR VICTOR OH
PRIMARY EXAMINER
12/8/07